

# Propalin Syrup

## Introduction



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## Presentation

A clear, colourless solution for oral use containing Phenylpropanolamine Hydrochloride PhEur 50 mg/ml.

## Uses

Phenylpropanolamine is a sympathomimetic agent which acts by direct stimulation of the  $\alpha$ -adrenergic receptors in the smooth muscle of the internal urethral sphincter. It is indicated in the treatment of urinary incontinence associated with urethral sphincter incompetence in the bitch. Efficacy has only been demonstrated in ovariohysterectomised bitches

## Dosage and administration

The recommended dose for Propalin is 1mg/kg bodyweight 3 times daily in the feed, corresponding to 0.1 ml Propalin Syrup / 5 kg bodyweight 3 times daily. The absorption rate is increased if the product is administered to fasted dogs.

## Contra-indications, warnings, etc

The use of Propalin is not appropriate for the treatment of behavioural causes of inappropriate urination. Do not administer to patients treated with non-selective monoamine oxidase inhibitors.

In the course of field clinical trials, loose stools, liquid diarrhoea, decrease in appetite, arrhythmia and collapse were reported in some dogs. Treatment was continued depending on the severity of the undesirable effect observed.

Sympathomimetics may produce a wide range of effects, most of which mimic the results of excessive stimulation of the sympathetic nervous system (e.g. effects on heart rate and blood pressure).

Phenylpropanolamine, a sympathomimetic drug, may affect the cardiovascular system, especially blood pressure and heart rate, and should be used with caution in animals with cardiovascular diseases.

Care should be exercised in treating animals with severe renal or hepatic insufficiency, diabetes mellitus, hyperadrenocorticism, glaucoma, hyperthyroidism or other metabolic disorders.

In bitches less than 1 year old the possibility of anatomical disorders contributing to incontinence should be considered prior to treatment.

Do not administer to pregnant or lactating bitches.

Care should be exercised in administering Propalin Syrup with other sympathomimetic drugs, anticholinergic drugs, tricyclic antidepressants or specific type B monoamine oxidase inhibitors. It should not be used in patients treated with non-selective monoamine oxidase inhibitors.

In healthy dogs, no side effects were observed at up to 5 times the recommended dosage. However, an overdose of phenylpropanolamine could produce symptoms of excessive stimulation of the sympathetic nervous system. Treatment should be symptomatic. Alpha-adrenergic blockers may be appropriate in the case of severe overdose. However, no specific recommendation on drugs or dosages can be given.

### *Withdrawal periods*

Not applicable

### *Operator warning*

Phenylpropanolamine Hydrochloride is toxic when overdoses are ingested. Adverse effects may include dizziness, headache, nausea, insomnia or restlessness, and increased blood pressure. High overdose may be fatal, especially in children.

To avoid accidental ingestion, the product must be used and kept out of reach of children. Always replace the cap securely after use. In the event of accidental ingestion, seek immediate medical attention showing the physician the package insert.

In the event of accidental skin contact, wash the contaminated area with soap and water. Wash hands after use of the product.

In the event of accidental eye contact, rinse the eye with clean water for about 15 minutes and seek medical advice.

## Pharmaceutical precautions

Do not store above 25°C. Do not refrigerate.

Following withdrawal of the first dose, use within 3 months. Discard any remaining product.

Any unused products or waste material should be disposed of in accordance with national requirements.

## Legal category

POM-V (previously POM)

**Packaging Quantities**

30ml and 100 ml: High density polyethylene bottle with low density polyethylene syringe adapter insert and a polypropylene child resistant closure; the package contains also one 2 ml graduated syringe of low density polyethylene /polystyrene.

**Further information**

None

**Marketing authorisation number**

Vm 08007/4035.